IN THE UNITED STATE PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Boyle, et al.	Attorney Docket No.:	6006-107
Serial No.:	10/672,695	Examiner:	Christopher D. Prone
Filed:	September 26, 2003	Art Unit:	3738
Title:	IMPLANTABLE GRAFT AND METHODS OF MAKING SAME		

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APPELLANT'S BRIEF ON APPEAL

1. Real Party in Interest

The real party interest for this patent application is Advanced Bio Prosthetic Surfaces, L.L.C., the assignee of the application.

2. Related Appeals and Interferences

The following appeals are pending in patent applications that are commonly owned with the present application. While the Applicants do not believe that these pending appeals will directly affect or be directly affected by the Board's decision in the present appeal, Applicants disclose these pending appeals due to the common ownership of the patent applications in question.

1. U.S. Patent Application Serial No. 09/707,685 to Palmaz et al., for Endoluminal Stent, Self-Supporting Endoluminal Graft and Methods of Making Same, filed on November 7, 2000. (Attorney Docket No. 6006-015)

2. U.S. Patent Application Serial No. 09/716,146 to Boyle et al., for Device for In Vivo Delivery of Bioactive Agents and method of Manufacture Thereof, filed on November 17, 2000. (Attorney Docket No. 6006-018)

3. U.S. Patent Application Serial No. 09/783,633 to Bailey et al., for In Vivo Sensor and Method of Making Same, filed on February 14, 2001. (Attorney Docket No. 6006-009)

4. U.S. Patent Application Serial No. 10/258,087 to Boyle et al., for Device for In Vivo Delivery of Bioactive Agents and Method of Manufacture Thereof, filed on August 19, 2003. (Attorney Docket No. 6006-070)

No decisions have been rendered by a court of by the Board in any of the aforementioned pending appeals identified pursuant to 37 C.F.R. § 41.37(c)(ii).

3. Status of Claims

Claims 7, 16, 17, 25, and 28 have been cancelled. Claims 13, 14, 32 and 33 have been withdrawn from consideration. Claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 are pending and stand rejected under 35 U.S.C. § 103(a). The rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 is under appeal.

4. Status of Amendments

Amendments to claims 1, 18, 21, 29, and 31 were filed after final rejection and were denied entry.

5. Summary of Claimed Subject Matter

Claims 1, 18, and 29 are independent claims in the pending application. Antecedent support for each element in claims 1, 18, and 29 is noted in the parentheses following each claim element:

Claim 1. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) having a pattern of microporous openings (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) passing therethrough;

(b) a metal structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) having at least one affixation member (page 18, line 30 – page 19, line 18; Figs. 1-3, 5, and 27), a pattern of openings (Figs. 3, 3a, and 27-40) passing through the metal structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) and underlying the microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) comprised of a metallic material (page 3, lines 23 – page 4, line 5); and

(c) wherein the metal structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) is attached to the microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) only at the at least one affixation member (page 18, line 30 – page 19, line 18; Figs. 1-3, 5, and 27).

Claim 18. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) comprised of a shape memory alloy having an austenite phase transition start temperature greater than 37° C (page 4, line 27 – page 5, line 3); and

(b) a structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) underlying the microporous covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) comprised of at least a pair of cylindrical elements (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) and interconnecting members (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) joining adjacent cylindrical elements (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40), the structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and

27-40) further comprised of a shape memory alloy having an austenite phase transition start temperature less than 0° C (page 4, line 27 – page 5, line 3);

(c) the structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) being attached to the microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) at least one point of attachment (page 18, line 30 – page 19, line 18; Figs. 1-3, 5, and 27) between the microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) and the structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40).

Claim 29. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) comprised of nitinol; and

(b) a structural support element (page 29, line 1 – page 30 line 6; Figs. 3, 3a, and 27-40) underlying the microporous covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) comprised of at least a pair of undulating cylindrical elements having a plurality of peaks and valleys and interconnecting members joining adjacent cylindrical elements at either the peaks or the valleys and having at least one projection (page 18, line 30 – page 19, line 18; Figs. 1-3, 5, and 27) extending longitudinally from a terminal cylindrical element, the structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) being comprised of nitinol (page 2, lines 3-5),

(c) the structural support element (page 29, line 1 – page 30, line 6; Figs. 3, 3a, and 27-40) being joined to the microporous metal thin film covering (page 22, line 27 – page 28, line 31; Figs. 4 and 6-26) at the at least one projection (page 18, line 30 – page 19, line 18; Figs. 1-3, 5, and 27).

6. Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 are unpatentable under 35 U.S.C. § 103(a) over EP 0 759 730 B1 to Burmeister et al. (hereinafter referred to as "Burmeister") in view of US 6,585,764 to Wright et al. (hereinafter referred to as "Wright").

7. Argument

The Examiner's obviousness rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to the claims on appeal because neither Burmeister nor Wright, either alone or in combination, teach or suggest a microporous metal thin film covering or an affixation element as recited in independent claims 1, 18, and 29. Applicants submit that independent claims 1, 18, and 29, and the claims that depend from independent claims 1, 18, and 29, dependent claims 3-6, 8-12, 15, 19-21, 23-24, 26, 27, 30-31, 34, and 35 depend from independent claims 1, 18, and 29 are nonobvious over the art cited and of record.

The claimed invention is generally directed to an endoluminal graft comprising a structural support element having at least one affixation member and a microporous metal thin film covering with a pattern of microporous openings passing through the metal thin film. In the Final Office Action mailed August 18, 2006, the Examiner fails to establish a *prima facie* case of obviousness because Burmeister and Wright, either alone or in combination, do not teach or suggest every limitation recited in independent claims 1, 18, and 29. More specifically, neither Burmeister nor Wright teaches: (a) a "microporous metal thin film covering," as is recited in independent claims 1, 18, and 29; or (b) an "affixation member", "point of attachment", or "projection," as recited in independent claims 1, 18, and 29, respectively.

A. "Microporous metal think film covering"

The Examiner asserts that Burmeister discloses "an implantable endoluminal graft comprising a nitinol thin film covering (34) having uniform pattern of elongated slots (figure 11a and 11b) and an underlying nitinol structural support element (32) that have multiple affixation elements throughout the device." (Final Office Action mailed August 18, 2006, page 2.) The Examiner recognizes that "Burmeister does not disclose that the thin metal film covering

comprises a microporous surface." (Final Office Action mailed August 18, 2006, page 3.) The Examiner, however, states that "Wright teaches the use of an implantable stent comprising a microporous outer surface." (Final Office Action mailed August 18, 2006, page 3.) The Examiner further concludes that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the microporous outer surface as taught by Wright with the implant of Burmeister in order to deliver a drug to the implant site." (Final Office Action mailed August 18, 2006, page 3.)

Applicants respectfully disagree with the Examiner's characterization of the prior art. First, Burmeister does not disclose an implantable endoluminal graft comprising a nitinol thin film covering as the Examiner asserts. Burmeister does not teach or suggest a structural support element with a separate metal thin film covering as recited in the claims on appeal. The Examiner refers to reference numeral 34 of Burmeister as the thin film covering. Reference numeral 34 is illustrated in Figure 3 of Burmeister. As Burmeister clearly explains, the stent illustrated in Figure 3 is a two layered stent, not a structural support element and a separate element comprising a thin film covering as required by the instant claims.

As explained in the application as filed, "[t]he thickness of the microporous metal thin film covering 17 may be between about 0.1 μm to about 20 μm, with a preferred range being between about 1 μm to about 10 μm, and a most preferred thickness being between about 1 μm and about 4.5 μm." (Boyle application as filed, p. 23, paragraph [00107], lines 12-14.) In contrast, Burmeister discloses "with reference to Figure 3, a layered construction may be provided in a stent 30." (Burmeister, column 6, paragraph [0029], lines 20-21.) Burmeister states that "[s]tent 30 is comprised of at least two layers 32 and 34." (Burmeister, column 6, paragraph [0030], lines 27-28.) Burmeister further explains that the stent construction need not even be comprised of two distinct layers. Burmeister teaches that "the two component concept of the invention may be embodied in two phases, *i.e.*, components of a single shape memory alloy and need not be in the form of two discrete components such as layers, members, wires, etc." (Burmeister, column 8, paragraph [0042], lines 41-44.) Burmeister does not teach or suggest a structural support element with a separate metal thin film covering as recited in the claims on appeal. Burmeister teaches only a stent, which could be compared only with the

structural support of the instant claims. There is nothing in Burmeister that teaches or suggests a separate metal thin film covering.

The Examiner then asserts that "Wright teaches the use of an implantable stent comprising a microporous outer surface." (Final Office Action, mailed August 18, 2006, page 3.) Applicants respectfully submit that the Examiner has misconstrued Wright. While Wright does use the term "micropores," the micropores of Wright do not correspond to the "microporous metal thin film covering having a pattern of microporous openings passing therethrough" as recited in the instant claims. The micropores of Wright are, in fact, reservoirs or depots, and are not actual holes passing through a thin film covering.

In the pending application, Applicants describe in detail the microporous metal thin film covering with holes or openings passing through the thickness of the metal thin film covering. For example:

> The microporous metal thin film covering 3 consists generally of a thin film metal covering material 17 having a plurality of micro-openings 19. The plurality of openings 19 preferably has an open surface area within the range of 0.5 μm to 150 μm, with the total open surface area being between 0.001 to 90%. The openings 19 permit cellular and sub-cellular physiological matter, such as proteins, to pass through the openings 19.
> (Boyle Application, page 21, paragraph [00103], lines 3-7, underlining added for emphasis.)

> Alternative embodiments of the present invention can have a varying size of each of the plurality of openings in the microporous metal thin film covering so that cellular migration occurs through each opening, without permitting fluid flow there through. In this manner, for example, blood cannot flow through the plurality of openings (in the deformed or un-deformed state), but various cells or proteins may freely pass through the plurality of openings to promote graft healing *in vivo*.
> (Boyle Application, page 22, paragraph [00104], lines 20-25, underlining added for emphasis.)

> A plurality of generally circular openings 256 pass through the metal thin film material 258 in an area bounded by a pair of circumferentially extending elongate slots 252 and a pair of circumferentially extending elongate slots 254.

(Boyle Application, page 28, paragraph [00124], lines 27-29, underlining added for emphasis.)

In contrast to the Applicant's structure of holes or openings, as described in the specification and recited in the claims, Wright discloses a stent with reservoirs or depots that do not transverse the thickness of the structural element. The micropores taught by Wright are actually indentations, not openings. In describing what Wright views as the novel element of the invention, Wright states that a "stent designed to include reservoirs is a new approach which offers several important advantages over existing technologies." (Wright, col. 3, lines 33-35, underlining added for emphasis.) Wright refers to the structure as "microporous depots." (Wright, col. 6, line 47, underlining added for emphasis.) Wright further explains that "[a]s seen in Figures 1a, 2, and 3a, any stent strut 10, 20, 30 can be modified to have a certain reservoir or channel 11, 21, 31." (Wright, col. 7, lines 18-20, underlining added for emphasis.) Wright also describes this structure in claim 12 which recites, in relevant part, "a channel formed in at least one of said struts, said channel having a closed perimeter on all sides and an open top." (Wright, col. 8, lines 37-39, underlining added for emphasis.)

Wright does not disclose a metal thin film covering, nor does Wright disclose any element that contains microporous passing therethough, as recited in claim 1. Figures Fig. 1a and Fig. 3b from Wright are reproduced below.

FIG. 1a

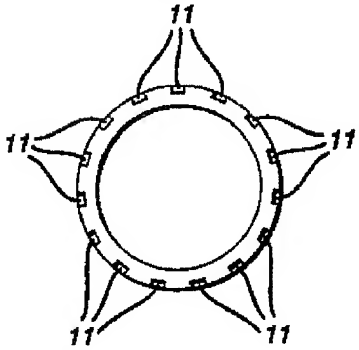
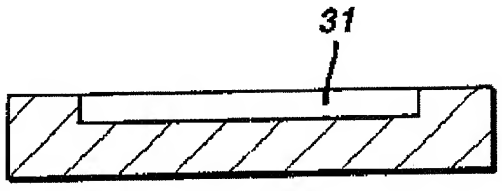


FIG. 3b



These figures illustrate the reservoirs or channels disclosed by Wright. As discussed above, and as clearly seen in the figures, Wright does not disclose a microporous metal thin film having microporous openings passing therethrough. Wright teaches a stent with structural elements possessing reservoirs or channels that do not form openings or transverse the thickness of the structural elements.

It is well established that an applicant is entitled to be his or her own lexicographer. (See MPEP § 2111.01 and § 2173.05(a).) "Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). MPEP § 2111.01. "When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). MPEP § 2173.05(a).

While Wright uses the term "micropore," Wright defines the term as a reservoir, having a closed perimeter on all sides and an open top. In contrast, the Applicants claim a "microporous metal thin film having a pattern of microporous openings passing therethrough." Clearly, Wright's micropores are not openings traversing the structural element in which they are located. If they were openings, as the Examiner seems to have mischaracterized them, Wright's invention would not work for its intended purpose. Wright discloses a stent that is coated with rapamycin. The micropores on the surface of Wright's stent are used as reservoirs to store the drug coating on the surface of the stent. If Wright's stent had openings similar to those of the Applicants, the drug coating would not remain stored in the reservoirs or depots on the outer surface of the stent as desired. The drug would pass through to the central lumen of the stent, and the drug would not be available for delivery.

The "microporous metal thin film covering having a pattern of microporous openings passing therethrough" represents a key feature of Applicants' invention. As disclosed in the application as filed (page 21, paragraph [00104]), Applicants' microporous metal thin film covering (also referred to as a graft) facilitates endothelialization of a graft-stent by promoting

cellular migration from the abluminal surface of the graft-stent, through the microporous openings, and into the luminal surface of the graft-stent. By facilitating endothelialization of the graft-stent, Applicant's graft-stent is capable of reducing the incidence of restenosis.

In contrast, the Examiner's combination of Burmeister and Wright would not be capable of achieving effective endothelialization because such a stent would not have microporous openings that transverse the metal thin film covering. Thus, cell migration from the abluminal surface to the luminal surface would be completely obstructed.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to the claims on appeal because neither Burmeister nor Wright, either alone or in combination, teach or suggest a microporous metal thin film covering as recited in independent claims 1, 18, and 29. The Examiner's rejection is, therefore, improper. Applicants respectfully submit that independent claims 1, 18, and 29 are allowable over the art cited and of record. Furthermore, if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 3-6, 8-12, 15, 19-21, 23-24, 26, 27, 30-31, 34, and 35 depend from independent claims 1, 18, and 29, and are, therefore, are also nonobvious over the art cited and of record.

B. "Affixation member", "point of attachment", or "projection"

The Examiner asserts that "Burmeister discloses the same invention being an implantable endoluminal graft comprising a nitinol film cover (34) having uniform pattern of elongated slots (figure 11a and 11b) and an underlying nitinol structural support element (32) that have multiple affixation elements throughout the device along the support elements cylindrical sinuous elements and the affixation projections shown in figures 1-16. (Final Office Action, mailed August 18, 2006, page 2, underlining added for emphasis.)

Contrary to the Examiner's assertion, Applicants submit that none of the embodiments illustrated or described in Burmeister disclose an "affixation member," "point of attachment," or "projection" (hereinafter collectively referred to as "affixation elements"), as recited in claims 1,

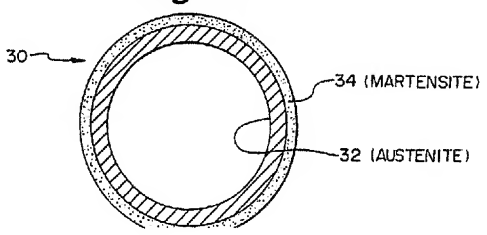
18, and 29, respectively. The Examiner refers generally to Figures 1-16 of Burmeister as disclosing affixation elements, but the Examiner fails to identify any single element disclosed in Burmeister that might correspond to an affixation element. The Examiner's rejection is so vague, that it is difficult to address with specificity. After reviewing figures 1-16 of Burmeister, it remains unclear to the Applicants what element of the Burmeister stent the Examiner identifies as an affixation element. While the Examiner cites figures 1-16 of Burmeister as disclosing affixation elements, many of figures 1-16 of Burmeister do not even illustrate stents. For example, figures 2, 4a, 4b, 7, 7a, 7b, 7c, and 7d of Burmeister are temperature transformation curves.

The Examiner argues that the "framework of Burmeister is being interpreted as having a plurality of affixation member, which are located at all points of contact between the film and the framework." (Final Office Action, mailed August 18, 2006, page 3.) Applicants respectfully disagree with the Examiner's characterization of Burmeister. Contrary to the Examiner's assertion, Burmeister does not even discloses any "points of contact." Neither the term "points of contact" nor any other term with a similar meaning even appears in Burmeister. Furthermore, Burmeister never discloses a film and a separate framework as the Examiner asserts. As discussed above, Burmeister discloses a stent that may have a layered construction. Nothing in Burmeister's stent with a layered construction corresponds to Applicants' affixation elements. More specifically, the "points of contact" that the Examiner interprets as being in Burmeister do not correspond to the "affixation member" of claim 1, the "point of attachment" of claim 18, or the "projection" of claim 29. The "points of contact" that the Examiner asserts are in Burmeister, even though Burmeister discloses no "points of contact", merely describe that the two layers of the Burmeister stent touch each other.

Although the Examiner's rejection as it relates to "points of contact" is extremely vague and fails to identify any structural element in Burmeister that would correspond to the Applicant's "affixation elements," the Applicant will address what Burmeister does, in fact disclose. The Examiner refers to Figure 3 of Burmeister by reciting elements and reference numerals from this figure. Figure 3 of Burmeister, reproduced below, illustrates a stent 30 with an outer layer 34 overlying an inner layer 32. The Burmeister stent lacks an affixation element, as recited in independent claims 1, 18, and 29. Instead, this embodiment of the Burmeister stent

30 has two layers and an interface between a martensitic layer 34 and an austenitic layer 32 of the stent. Contrary to the Examiner's suggestion, an interface between two layers of a bi-layered stent does not constitute an affixation element.

Fig. 3



Burmeister explains that "with reference to Figure 3, a layered construction may be provided in a stent 30." (Burmeister, column 6, paragraph [0029], lines 20-21.) Burmeister states that "[s]tent 30 is comprised of at least two layers 32 and 34." (Burmeister, column 6, paragraph [0030], lines 27-28.) Burmeister further explains that the stent construction need not even be comprised of two distinct layers. Burmeister teaches that "the two component concept of the invention may be embodied in two phases, *i.e.*, components of a single shape memory alloy and need not be in the form of two discrete components such as layers, members, wires, etc." (Burmeister, column 8, paragraph [0042], lines 41-44, underlining added for emphasis.) Burmeister does not teach or suggest an "affixation element." as recited in the claims on appeal. Burmeister does not even teach "points of contact" as the Examiner alleges.

In contrast to the "points of attachment' that the Examiner alleges are in the Burmeister stent, the claims on appeal require an actual element described as an "affixation member", a "point of attachment", or a "projection". The claims of the present application require (a) a structural support element, (b) a microporous metal thin film, and (c) an affixation element where the structural support element and the microporous metal thin film are attached to one another. Neither (b) a microporous metal thin film, nor (c) an affixation element where the structural support element and the microporous metal thin film are attached to one another are present in Burmeister.

As described in the present application as filed, the claimed affixation element requires the physical joining of the microporous thin film covering and the structural support element.

> Another aspect of the present invention is an implantable endoluminal graft wherein the structural support element is physically attached to the microporous thin film covering at least one point of contact between the microporous thin film covering and the structural support element. Preferably, the at least one point of contact is located at either near a proximal end or distal end of the microporous thin film covering and corresponding end of the structural support element. Even more preferably, the at least one point of contact is located at near a distal end of the microporous thin film covering and structural support element. The physical attachment of the structural support element to the microporous thin film covering is accomplished by using a spot weld, a suture, adhesive, or other means of **physically joining the two elements**.
> (Boyle Application, page 5, paragraph [0013], lines 4-13, underlining and bold added for emphasis.)

> In accordance with the present invention, an implantable endoluminal graft is provided that is comprised of two main features: a microporous thin film covering and an underlying structural support member, which are physically connected to one another.
> (Boyle Application, page 11, paragraph [0068], lines 18-20, underlining added for emphasis.)

Burmeister does not disclose two separate elements of a thin film covering and a structural support element. Since Burmeister does not even disclose these two separate elements, it is understandable that Burmeister also fails to disclose the physical joining if the two elements.

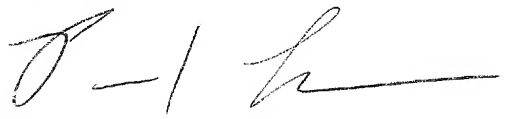
In order to establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested in the prior art. MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). Neither Burmeister nor Wright, either alone or in combination, provide each element of the claimed invention. The combination of cited art does not teach or suggest an affixation element that attaches a microporous metal thin film covering to a structural support element. The Examiner's rejection is, therefore, improper. Applicants submit that independent claims 1, 18, and 29 are patentable over the art cited and of record. Similarly, if an independent claim is nonobvious under 35 U.S.C. §103(a), any claims depending from that

independent claim are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Accordingly, Applicants submit that dependent claims 3-6, 8-12, 15, 19-21, 23-24, 26, 27, 30-31, 34 and 35 are also nonobvious.

Conclusion

An obviousness rejection under 35 U.S.C. §103(a) requires that the cited prior art references must disclose each and every claimed element. Neither Burmeister nor Wright, either alone or in combination, teach or suggest every limitation recited in the pending claims on appeal. The cited references do not render the pending claims obvious, and the Examiner's rejection is improper. Accordingly, Applicants submit that pending claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 are patentable over the art cited and of record.

Respectfully submitted,



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8. Claims Appendix

The following is a listing of the claims on appeal.

1. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering having a pattern of microporous openings passing therethrough;

(b) a metal structural support element having at least one affixation member, a pattern of openings passing through the metal structural support element and underlying the microporous metal thin film covering comprised of a metallic material; and

(c) wherein the metal structural support element is attached to the microporous metal thin film covering only at the at least one affixation member.

2. The implantable endoluminal graft of claim 1, wherein the affixation member is positioned near either a proximal end or distal end of the microporous metal thin film covering and a corresponding end of the metal structural support element.

3. The implantable endoluminal graft of claim 1, wherein the affixation member is near a distal end of the microporous metal thin film covering and metal structural support element.

4. The implantable endoluminal graft according to claim 1, wherein the at least one affixation member is positioned near a terminal end of the metal structural support element.

5. The implantable endoluminal graft of claim 4, wherein the microporous metal thin film covering is attached to the at least one affixation member.

6. The implantable endoluminal graft of claim 1, wherein the cylindrical elements have a sinusoidal pattern with alternating peaks and valleys.

7. (Cancelled).

8. The implantable endoluminal graft according to claim 4, wherein the metal structural support element further comprises a plurality of cylindrical elements and interconnecting elements, the cylindrical elements adopting a sinusoidal pattern with alternating peaks and valleys and the at least one affixation member extends longitudinally from at least one of a peak or a valley at a terminal end of the metal structural support element.

9. The implantable endoluminal graft of claim 8, wherein the microporous metal thin film covering exhibits a uniform pattern of openings throughout the surface of the microporous metal thin film covering.

10. The implantable endoluminal graft of claim 9, wherein the microporous metal thin film covering and the metal structural support element are fabricated from nitinol.

11. The implantable endoluminal graft of claim 10, wherein the microporous metal thin film covering maintains a martensite crystalline structure throughout a temperature transition from room temperature to body temperature and behaves martensitically *in vivo*.

12. The implantable endoluminal graft of claim 10, wherein the metal structural support element undergoes a martensite to austenite phase transition, during a temperature transition from room temperature to body temperature and behaves austenitically *in vivo*.

13. (Withdrawn) The implantable endoluminal graft of claim 10, further comprising a microporous metal thin film covering that maintains an austenite crystalline structure throughout a temperature transition from room temperature to body temperature and behaves austenitically *in vivo*.

14. (Withdrawn) The implantable endoluminal graft of claim 10, further comprising a microporous metal thin film covering that undergoes a phase transition, from martensite to austenite crystal structure, during a temperature transition from room temperature to body temperature and behaves austenitically *in vivo*.

15. The implantable endoluminal graft of claim 1, wherein the at least one affixation member comprises a projection projecting proximally or distally from a cylindrical element at a terminal end of the structural support member.

16. (Cancelled).

17. (Cancelled).

18. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering comprised of a shape memory alloy having an austenite phase transition start temperature greater than 37° C; and

(b) a structural support element underlying the microporous covering comprised of at least a pair of cylindrical elements and interconnecting members joining adjacent cylindrical elements, the structural support element further comprised of a shape memory alloy having an austenite phase transition start temperature less than 0° C;

(c) the structural support element being attached to the microporous metal thin film covering at least one point of attachment between the microporous metal thin film covering and the structural support element.

19. The implantable endoluminal graft of claim 18, wherein the shape memory alloy is nitinol.

20. The implantable endoluminal graft of claim 18, wherein the microporous metal thin film covering maintains a martensite crystalline structure throughout the temperature transition from room temperature to body temperature.

21. The implantable endoluminal graft of claim 18, further comprising a structural support member that undergoes a phase transition, from martensite to austenite crystal structure, during the temperature transition from room temperature to body temperature.

22. The implantable endoluminal graft of claim 18, wherein the at least one point of contact is located at either near a proximal end or distal end of the microporous metal thin film covering and corresponding end of the structural support element.

23. The implantable endoluminal graft of claim 18, wherein the at least one point of contact is located at near a distal end of the microporous metal thin film covering and structural support element.

24. The implantable endoluminal graft of claim 18, wherein the cylindrical elements adopt a sinusoidal pattern with alternating peaks and valleys.

25. (Cancelled).

26. The implantable endoluminal graft of claim 18, wherein the microporous metal thin film covering exhibits a uniform pattern of openings throughout the surface of the microporous metal thin film covering.

27. The implantable endoluminal graft of claim 18, wherein the at least one point of contact is on a terminal end of a terminal interconnecting member.

28. (Cancelled)

29. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering comprised of nitinol; and

(b) a structural support element underlying the microporous covering comprised of at least a pair of undulating cylindrical elements having a plurality of peaks and valleys and interconnecting members joining adjacent cylindrical elements at either the peaks or the valleys and having at least one projection extending longitudinally from a terminal cylindrical element, the structural support element being comprised of nitinol,

(c) the structural support element being joined to the microporous metal thin film covering at the at least one projection.

30. The implantable endoluminal graft of claim 29, wherein the microporous metal thin film covering maintains a martensite crystalline structure throughout the temperature transition from room temperature to body temperature.

31. The implantable endoluminal graft of claim 29, wherein the structural support member that undergoes a phase transition, from martensite to austenite crystal structure, during the temperature transition from room temperature to body temperature.

32. (Withdrawn) The implantable endoluminal graft of claim 29, further comprising a microporous metal thin film covering that maintains an austenite crystalline structure throughout a temperature transition from room temperature to body temperature and behaves austenitically *in vivo*.

33. (Withdrawn) The implantable endoluminal graft of claim 29, further comprising a microporous metal thin film covering that undergoes a phase transition, from martensite to austenite crystal structure, during a temperature transition from room temperature to body temperature and behaves austenitically *in vivo*.

34. The implantable endoluminal graft of claim 29, wherein the microporous metal thin film covering exhibits a regular pattern of openings throughout a surface of the microporous metal thin film covering.

35. The implantable endoluminal graft of Claim 34, wherein the regular pattern of openings further comprises a plurality of elongate slots arrayed in circumferentially adjacent and longitudinally offset rows, each of the plurality of elongate slots being parallel to a longitudinal axis of the endoluminal graft and capable of opening under the influence of a circumferentially expansive force.

9. Evidence Appendix

None.

10. Related Proceedings Appendix

None. No decisions have been rendered by a court or by the Board in any of the pending appeals identified under Related Appeals and Interferences pursuant to 37 C.F.R. § 41.37(c)(ii).